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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,476	11/25/2003	Edward J. Gough	A-70576/ENB	7642
32940 7590 09/07/2007 DORSEY & WHITNEY LLP 555 CALIFORNIA STREET, SUITE 1000 SUITE 1000 SAN FRANCISCO, CA 94104			EXAMINER BOUCHELLE, LAURA A	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/723,476

### Applicant(s)

GOUGH ET AL.

### Examiner

Laura A. Bouchelle

### Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/18/2007 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Silverman et al (US 6251063). Silverman discloses an injection device comprising a probe 22, a first tubular member 31 insertable into the probe, a second tubular member 62 slidable within first tubular member, the second tubular member being provided with a needle 61. The needle can be made of metal and the tubular members can be made of plastic (Col. 4, line 66 – Col. 5, line 1, Col. 5, lines 17-20). The needle 61 has a bevel (Col. 5, lines 20-25). Silverman discloses the solution of

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a biocompatible composition and a biocompatible solvent as claimed (Col. 9, lines 35-45). A reservoir 92 contains the solution.

***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1- 3, 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al (US 6251063) in view of Astarita (US 6228059) in view of Stack et al (US 2001/0051822).

6. Claim 1 differs from Silverman in calling for a lock to lock the second tubular member relative to the first tubular member. Astarita teaches an endoscopic instrument having a locking mechanism to lock the inner tubular member relative to the outer tubular member so that the inner tubular member may be fixed safely and easily by a surgeon during complicated procedures (See Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman to include a locking mechanism as taught by Astarita so that the inner tubular member may be fixed safely and easily by a surgeon during complicated procedures.

7. Claim 1 further differs from the teachings above in calling for the second tubular member to have sufficient column strength to prevent buckling and provide substantially one-to-one movement between the proximal and distal extremities of the second tubular member. Stack teaches a insertion device comprising a first tubular member 22 and an inner second tubular member 21, the inner member having sufficient column strength to prevent buckling or

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deformation so that the distal end of the inner tubular member can be precisely placed within the body (Page 5, Paragraph 0049). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman in view of Astarita so that the second tubular member has sufficient column strength to prevent buckling as taught by Stack so that the distal end of the second tubular member can be precisely placed within the body.

8. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman in view of Astarita in view of Stack as applied to claim 3 above, and further in view of Kikawada (US 5637075).

9. Claim 4 differs from the teachings above in calling for a first and second optical element. Claim 5 differs in calling for the optical element to have an inclined end surface. Kikawada teaches a device for observing the inside of a body cavity having a first optical element for supplying light and a second optical element for receiving reflected light that allows for the physician to visualize the body cavity to facilitate proper placement of the medical device (Col. 1, lines 30-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman in view of Astarita in view of Stack to have a first and second optical element as taught by Kikawada the physician can visualize the body cavity to facilitate proper placement of the medical device.

10. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman in view of Astarita in view of Stack as applied to claim 1 above, and further in view of Morrison (US 4609370).

11. Claim 6 differs from the teachings above in calling for the needle to have a distal face inclined at an angle greater than 25 degrees. Claim 7 calls for the angle to be approximately 30 degrees. Morrison teaches a needle assembly having a needle with an angle of approximately thirty degrees to allow for easy insertion into the tissue (Col. 5, lines 20-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman in view of Astarita in view of Stack to have a needle with an incline of approximately thirty degrees as taught by Morrison to allow for easy insertion into the tissue.

#### ***Response to Arguments***

12. Applicant's arguments, see pages 8-9, filed 7/18/07, with respect to the rejection(s) of claim(s) 1 under Silverman I in view of Astarita in view of Silverman II have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Silverman in view of Astarita in view of Stack as above.

#### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle  
Examiner  
Art Unit 3763



NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER